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# Healthcare & Life Sciences Update: The Netherlands

The legal landscape for companies active in the Dutch healthcare and life sciences sector is ever-changing. Recent changes include: the broadening of the duty to report serious adverse events in medical research, the amended assessment of non-interventional studies, and the new rules regarding online sales of pharmaceuticals. This edition of our Healthcare & Life Sciences Update highlights some of the latest developments in regulations and enforcement which may impact your business.

## Use of BIG-number extended to Transparency Register

As of 1 September 2015 the Individual Healthcare Professions Registration Decree (*Registratiebesluit BIG*) has been amended so that the healthcare professional registration number (or the BIG-number) can be used by the Healthcare Transparency Register (*Transparantie-register Zorg*). The Transparency Register was launched in April 2013, initially on a self-regulatory basis, for the purpose of disclosing the financial relations between healthcare professionals and the healthcare industry.

In addition, pharmaceutical companies as well as manufacturers and resellers of medical devices have to use the BIG-number when reporting their financial relations with healthcare professionals to the Transparency Register. This obligation will come into force on a date yet to be determined, as laid down in the Medicines Act Decree (*Besluit Geneesmiddelenwet*) and Medical Devices Decree (*Besluit medische hulpmiddelen*).

The amendments are set out in the Decree dated 24 Augustus 2015 amending the Medicines Act Decree, the Medical Devices Decree and the Individual Healthcare Professions Registration Decree. The aim of the amendments is to provide a legal basis for this extended use of the BIG-number, as the Data Protection Act (*Wet bescherming persoonsgegevens*) requires such a solid basis for the use of a number prescribed by law identifying a person.

## Broadening of duty to report serious adverse events

With effect from 1 October 2015 an amendment to the Medical Research Act (*Wet medisch-wetenschappelijk onderzoek met mensen*) has come into force that broadens the obligation to report serious adverse events. The duty to report serious adverse events is now not only required for clinical trials on medicinal products but mandatory for all types of medical research; experience shows that the same risks apply to medical research regarding ia food, medical devices, radiation, and surgical procedures.

Due to the amendment of the Medical Research Act, a new Regulation of the Minister of Healthcare, Welfare and Sport dated 9 July 2015 containing rules for medical research with people (*Regeling medisch-wetenschappelijk onderzoek met mensen*) has been introduced. Pursuant to the new regulation, the Central Committee on Research Involving Human Subjects (*Centrale Commissie Mensgebonden Onderzoek, CCMO*) needs to report on serious adverse events annually. To enable the CCMO to do so researchers need to report the events on the online portal 'Toetsing Online'.

In addition, for clarity's sake, the new regulation merges two existing regulations based on the Medical Research Act, namely the Scientific Research with Medicines Regulation (*Regeling wetenschappelijk onderzoek met geneesmiddelen*) and the Supervision WMO Regulation (*Regeling toezicht WMO*).

## Mandatory insurance for medical research

Pursuant to a new Decree dated 24 November 2014, containing rules on mandatory insurance for medical research with human subjects (*Besluit verplichte verzekering bij medisch-wetenschappelijk onderzoek met mensen 2015*), which is based on the Medical Research Act, it is mandatory to have in place a direct insurance for participants of medical research. The Decree came into force on 1 July 2015.

The Decree contains additional criteria regarding such insurance. The rules mainly focus on the term of the insurance (during participation and within 4 years after termination of the participation), the amounts covered by the insurance (between EUR 650,000 and EUR 5,000,000 per trial) and the relationship between the participants and the insurer (nullity, defenses and expiration of the insurance cannot be invoked unless the participant has given his/her consent).

## Tightening of duplex authorisation procedure

The Dutch Medicines Evaluation Board (*College ter Beoordeling van Geneesmiddelen*, *CBG-MEB*), the authority responsible for registration of medicinal products, has decided to alter the duplex marketing authorisation procedure. This in order to make it a simple administrative act without the need for substantive assessment. Due to these changes, as of 1 September 2015, the duplex application can only be filed for pharmaceuticals which, at the time of the application: (i) have been registered for a maximum period of 5 years, or for which a mutual recognition procedure has been successfully completed no longer than 5 years ago (the Netherlands as the reference country, day 90 is no more than 5 years ago), and (ii) have an approved risk management plan.

The duplex procedure is only available for pharmaceuticals which have been registered more than 5 years ago and if the following additional conditions are met: (i) the file of the duplex product stays identical to the file of the original product after granting the authorization, (ii) it is not possible to initiate a mutual recognition procedure for the duplex product, (iii) the authorisation of the duplex product cannot be transferred to another (legal) entity, and (iv) if the authorisation of the original product is cancelled, a cancellation request for the authorisation of the duplex product needs to be filed within 3 months.

## Changes to policies on product information

On 31 Augustus 2015, the Medicines Evaluation Board (*College ter Beoordeling van Geneesmiddelen*, *CBG-MEB*) also amended its policy on the information leaflet of pharmaceutical products, its policy on the labelling of pharmaceutical products and its explanation of the guideline on the Summary of Product Characteristics dated September 2009.

The most important amendments to the policies concern blister holders, QR codes and bar codes, amendments to the requirements for cartons with blank label stickers, requirements regarding leaflets for children, the inclusion of information about self-administration at home, information about recording a contra-indicated interaction with a medicines group and information about compatibility with other products or solutions.

## Amendments of the inducement self-assessment

Since 1 May 2014 the inducement self-assessment is a mandatory element of the accreditation application for continuous professional development meetings with specialists in family medicine (*huisartsgeneeskunde*), general (internal) medicine (*interne geneeskunde*) and orthopaedics (*orthopedie*). Based on the self-assessment it is determined whether such meetings, which are (also) financed by the pharmaceutical or medical devices companies, comply with the rules for the sponsoring of events as set out by the self-regulating body Foundation for the Code for Pharmaceutical Advertising (*Stichting Code Geneesmiddelenreclame; CGR*).

As of 1 July 2015 costs are charged to the applicant when the application cannot be approved automatically. Furthermore, the mandatory self-assessment will gradually be extended to continuous professional development meetings focused on other specialists as well.

## Amended review of non-interventional studies

On 1 January 2015 the new review framework for non-interventional studies (*Toetsingskader niet-WMO plichtig onderzoek*) entered into force. The transitional period for the review of non-interventional studies on the basis of the Code of Conduct for Pharmaceutical Advertising (*Gedragscode Geneesmiddelenreclame*) has ended on 1 July 2015, which means that the approval of the business-related Standard Operating Procedures no longer applies.

As of 1 July 2015 each individual non-interventional study, which is initiated by a pharmaceutical company, must be preventively reviewed by the Inspection Board. The application form needs to be sent to the Inspection Board by e-mail (cgr@cgr.nl).The costs associated with the preventive review are EUR 2,000 (excluding VAT). The Inspection Board strives to send its opinion to the applicant within six weeks.

## Accessibility and affordability of pharmaceuticals

The Dutch Healthcare Authority (*Nederlandse Zorgautoriteit*, *NZa*), the supervisory body for the healthcare markets in the Netherlands, has published its report regarding the accessibility and affordability of pharmaceuticals in specialist medical care as increasingly expensive pharmaceuticals become available to specialists. Many hospitals have indicated that they will soon be unable to buy these pharmaceuticals due to the high costs associated with them.

To improve the accessibility and affordability of these pharmaceuticals in the (near) future, the Dutch Healthcare Authority has provided some recommendations: (i) assess the effectiveness and costs of a medicinal product in advance (before it is available to medical specialists); (ii) create procurement power in order to obtain the bargaining position of hospitals, healthcare insurers, etcetera ; (iii) the government must set statutory maximum prices which need to be adjusted when the patient population that uses this product increases; (iv) evaluate the relevant European and national regulations to prevent unintended side effects and obstructions; and (v) continue the search for alternatives and the proper dosage, such as 'biosimilars' as alternative to the more expensive 'biologicals' and packaging that matches the proper dosage.

So far the National Healthcare Reporting Centre (*Landelijk Meldpunt Zorg*) has not received any reports on financial issues regarding the prescription of expensive pharmaceuticals.

## New rules regarding online sales of pharmaceuticals

To prevent counterfeit medicinal products from entering the supply chain, the European Parliament and the European Council adopted Directive 2011/62/EU (the so-called Counterfeit Directive). Based on the Counterfeit Directive and European Implementation Regulation 699/2014, a European logo for providers of online pharmaceuticals and a government website providing an overview of online providers have been introduced. In the Netherlands, these new rules have been implemented into the Dutch Medicines Act (*Geneesmiddelenwet*) (Articles 67a and 67b) and Medicines Act Regulation (*Regeling Geneesmiddelenwet*) (Articles 6.12 and 6.13).

Based on the Dutch rules, the providers of online pharmaceuticals need to register with the CIBG, an implementing body of the Dutch government which collects, processes and distributes healthcare related (certified) data. After the provider has filed a registration request with the CIBG, the CIBG will check whether the provider sells products which are legally allowed to be sold. If so, the provider will be registered with the CIBG and included in a list of providers which is available on the official website: www.aanbiedersmedicijnen.nl.
The provider will receive a logo which it needs to place on its website.

## Joint procurement of healthcare products

With regard to the procurement of healthcare products and services, the Netherlands, together with Belgium and Luxembourg, has initiated joint price negotiations as it anticipates that collectively the countries will have a better bargaining position. According to a recent appeal made by the Minister of Health, Welfare and Sports, joint negotiations by countries, together with greater transparency of the cost structure of expensive pharmaceuticals, are topics that will have high priority when

the Netherlands chairs the Council of the European Union in the first half of 2016.

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